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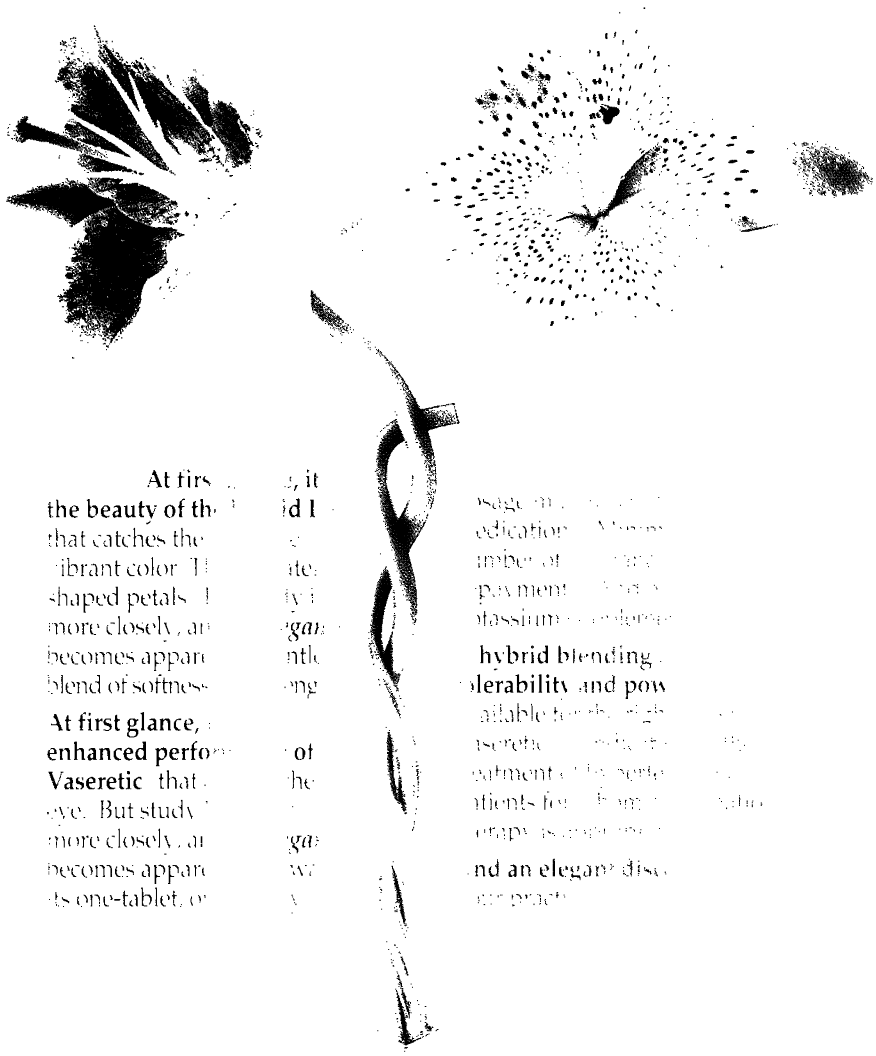

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VASERETIC 10-25 *Next*
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TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

10 mg

25 mg

CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General; Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions,* and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. This may occur at any time during treatment. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide).*

Pregnancy; Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality,* below.)

Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats, and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5. 6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate; Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent preexisting renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium).*

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur at any time during treatment with angiotensin converting enzyme inhibitors, including enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions; Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide; When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution

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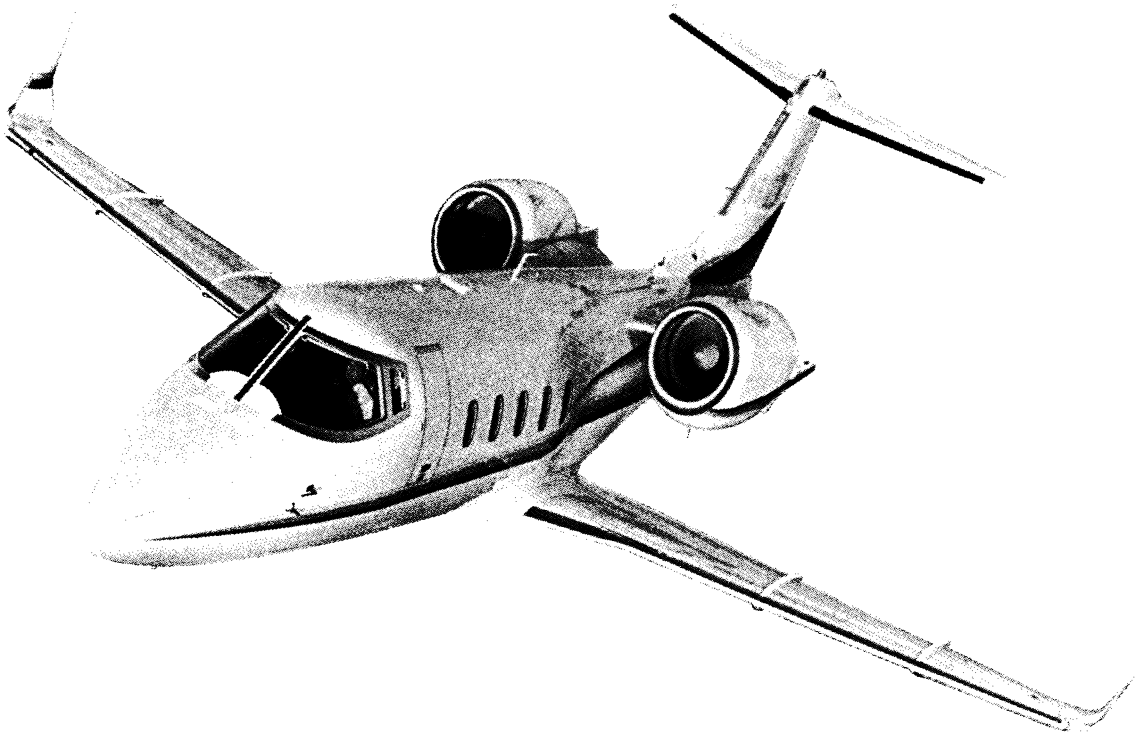

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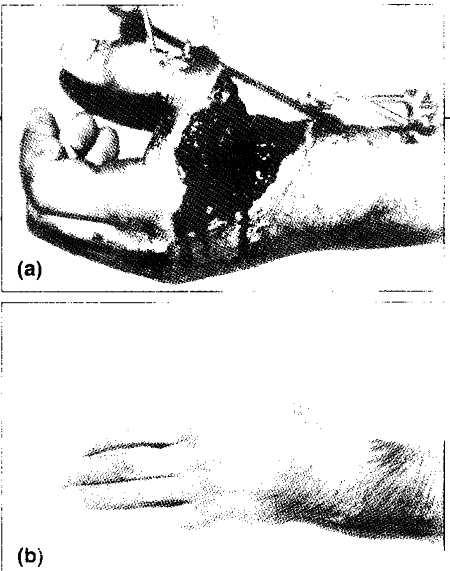

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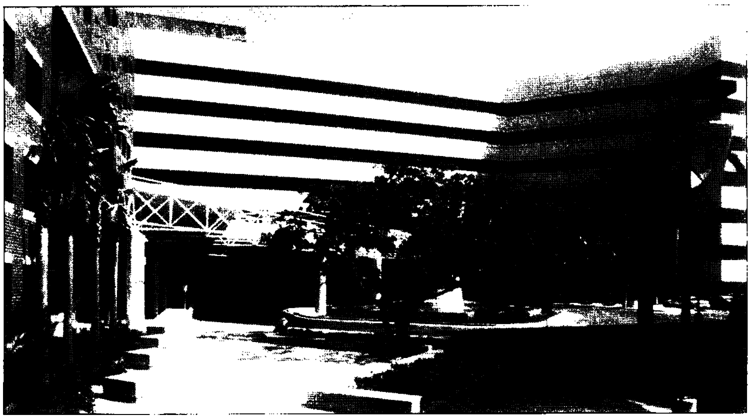

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The oromandibular region is particularly complex. Through advances in techniques and instrumentation, reconstructive surgeons can move the forehead, change the position of the eyes, realign the jaws and reshape the underlying structure to make dramatic differences in craniofacial deformities.

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Patients who require extensive disfiguring tumor resection are benefitted by advances in microvascular techniques and osseointegrated implants for facial prosthetic reconstruction. In addition, musculoskeletal tumors in the upper and lower extremities that once required amputation may be treated through limb salvage procedures that incorporate antibiotic therapy, tumor resection, immediate implantation of bone allograft or endoprostheses, and microvascular coverage using free tissue transfer.

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APRIL 15-17, 1994

ADDICTION MEDICINE
LOCATION: New Orleans, Louisiana
SPECIALTY: Primary Care, Psychiatry, Emergency Medicine
CME CREDIT: AMA Category I, 15 hours
FEE: SMA Member $350; Nonmember $475

APRIL 15-17, 1994

ORTHOPAEDIC UPDATE
LOCATION: Wrightsville Beach, NC
SPECIALTY: Orthopaedic Surgery
CME CREDIT: AMA Category I, 14 hours
FEE: SOA Member $125; SMA Member $225; Nonmember $350

APRIL 22-24, 1994

INFECTIOUS DISEASES
LOCATION: Atlanta, Georgia
SPECIALTY: Primary Care
CME CREDIT: AMA Category I, 15 hours
FEE: SMA Member $310; Nonmember $435

MAY 20-22, 1994

CURRENT CONCEPTS IN ORTHOPAEDICS
LOCATION: Baltimore, Maryland
SPECIALTY: Orthopaedic Surgery
CME CREDIT: AMA Category I
FEE: SOA Member $175; SMA Member $275; Nonmember $400; Resident or Fellow $50; Nonphysician $75

JUNE 9-11, 1994

SOUTHERN ASSOCIATION FOR GERIATRIC MEDICINE, FOURTH ANNUAL MEETING
LOCATION: Hilton Head, South Carolina
SPECIALTY: Geriatrics
CME CREDIT: AMA Category I
FEE: To be announced

JUNE 12-16, 1994

EIGHTEENTH SYMPOSIUM ON LUNG DISEASE
LOCATION: Sea Island, Georgia
SPECIALTY: Pulmonary and Critical Care Medicine
CME CREDIT: AMA Category I, 22 hours
FEE: SMA/Southern ACCP Member $415; Nonmember $540; Nonphysician $275

JUNE 16-18, 1994

MUSCULOSKELETAL IMAGING
LOCATION: Nevis, Caribbean
SPECIALTY: Radiology
CME CREDIT: AMA Category I, 17 hours
FEE: SMA Member $395; Nonmember $520; Nonphysician $275

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THE DIVISION OF FAMILY MEDICINE AT THE UNIVERSITY OF CALIFORNIA, SAN DIEGO is seeking faculty members interested in combining clinical practice with clinical teaching. The positions will be at the Assistant Professor level, non-tenure track. The positions involve participating in a growing community-based, full spectrum Family Practice in a multicultural community with a full range of ages, socioeconomic, and health care payor systems. Opportunities for student and resident training are incorporated in the role. Candidates should be BC in Family Medicine with a strong commitment to teaching, clinical practice, and scholarship. Rank and salary, commensurate with qualifications and experience, based on UC scale. Interested candidates should send a CV and names of three references to:

UCSD
David Baughan, MD
Associate Clinical Professor
Division of Family Medicine (0807)
9500 Gilman Dr
La Jolla, CA 92093-0807

UCSD is an equal opportunity/affirmative action employer. All applications received by April 30 or thereafter until position is filled will receive thorough consideration.

NO HURRICANES, NO EARTHQUAKES! Just fresh air and happy living in north Idaho. An opportunity for a Primary Physician, Internist, Rheumatologist, Family Practitioner, or General Practitioner to take over an established practice at a minimal cost. Well equipped office, adjoining certified lab, experienced staff. New 170-bed hospital has state-of-the-art diagnostic and treatment facilities. Located in the foothills of the Rockies, Coeur d'Alene is a town of 25,000, a center of outdoor recreation, sports, and cultural activity. Please call Kelly at (208) 664-9234.

FAMILY PRACTICE. SALEM, OREGON. 20 plus multispecialty group in Oregon's beautiful Willamette Valley seeks BC/BE Family Practice physician. No OB. Good call rotation. Salary plus incentive, outstanding benefits. 45 minutes from Portland. Savor city life without the headaches. Natural wonders and recreational amenities abound. Contact Yvonne Carscadden at (503) 399-2470 or send CV to Salem Clinic, 2020 Capitol NE, Salem, OR 97303.

HAWAII. FAMILY PRACTITIONER needed for rural Oahu. Full-time position in nonprofit community health center. Desire dedication to work in multicultural setting. Obstetric skills preferred. Send letter and CV to Puanani Kalawa. Waianae Coast Comprehensive Health Center, 86-260 Farrington Highway, Waianae, HI 96792; (808) 696-7081.

SIMPLY THE BEST LOCUM TENENS PLACEMENT OPPORTUNITIES nationwide for Internal Medicine, Pediatrics, and Family Practice. Try a practice before you sign. Call The Locums' Company today at (800) 735-6286.

SOUTHERN CALIFORNIA. Great private practice opportunity in an affluent Orange county community. Primary Care practice with tremendous growth potential. BC in Family Practice or Emergency Medicine. Contact Dr. Joss, (714) 777-1773 or send CV to 21580 Yorba Linda Blvd, #102, Yorba Linda, CA 92687.

PHYSICIANS WANTED

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If your goals include a quality lifestyle, a dynamic medical community, excellent schools/universities, and beautiful and affordable housing, then we have the ideal practice opportunity for you!

HOLY FAMILY HOSPITAL and the MEDICAL STAFF are working together to meet the healthcare demands of our 150,000 patient population. There is an IMMEDIATE need for BC/BE physicians in the following specialties:

- FAMILY PRACTICE
- INTERNAL MEDICINE
- GENERAL SURGERY
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SPOKANE, WASHINGTON (370K metro population) is the regional Healthcare and Cultural center offering a sound economy, unlimited outdoor recreation and a mild four season climate.

CONTACT with CV to: **Nancy Chaffins**

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FAX: (509) 482-2187

FAMILY PHYSICIAN–LEWISTON, IDAHO
Opportunity to join Family Practice group. Ambulatory and acute/inpatient care. No OB. Competitive income guarantee with opportunity to join full partnership. Send CV to Clearwater Medical Clinic, 1522 17th St, Lewiston, ID 83501, attn: Peggy Johnson; or call (208) 743-8416.

NORTHERN CALIFORNIA RECREATION AREA. Multispecialty group has immediate opening for an Internal Medicine practitioner with a particular interest in Critical Care. Clinical activities involve full range of Internal Medicine outpatient and inpatient practice. Beautiful northern California location offers abundant recreational opportunities as well as small town living. Competitive salary and comprehensive benefit package. Please send CV to 10978 Donner Pass Rd, Truckee, CA 96161.

SPOKANE, WASHINGTON OPPORTUNITY for BC/BE Family Practitioners and Pediatricians. Come enjoy this mild four season climate with unlimited year-round recreation. Take advantage of the excellent schools, universities, and affordable housing. Join this well established and growing multispecialty group offering choice practice opportunities within our satellite clinics. Advantages: favorable call schedules; an excellent benefits package and salary leading to early shareholder status; six weeks vacation and paid CME. Contact: Colleen Mooney; Rockwood Clinic; E 400 Fifth Ave, Spokane, WA 99202; (509) 838-2531, FAX (509) 455-5315.

(Continued on Page 391)

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PHYSICIANS WANTED

NORTHWEST REGION

Physicians needed to join a multispecialty group, partnership, or solo practice, due to the explosive population growth. BC/BE physician specialties:

- FAMILY PRACTICE
- PEDIATRICS
- CARDIOLOGY
- PSYCHIATRY
- INTERNAL MEDICINE
- ORTHOPEDICS

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Marge Becker, Owner/Manager
BECKER PHYSICIAN PLACEMENT
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(800) 945-4066/FAX (509) 484-6317

INTERNIST/FAMILY PRACTICE. Physician for well loved multidisciplinary Geriatric Health Center. Part of East San Francisco bay area community clinic network. Locum tenens position available. 60% time. Participation in hospital and call coverage desired. Resident teaching and UCSF clinical affiliation possible. Call (510) 644-6060.

CALIFORNIA–SAN LUIS OBISPO AREA. Position available in Urgent Care center on the beautiful central California coast. Competitive compensation, malpractice paid. Prefer physicians with experience or residency training in Emergency Medicine or Family Practice. Send CV to Medical Director, 283 Madonna Rd, Ste B, San Luis Obispo, CA 93405.

BC OR RECENTLY BE PHYSICIANS NEEDED. Los Angeles and Seattle metropolitan areas: Family Practice, Pediatrics, OB/GYN, Industrial Medicine, Urgent Care, and Internal Medicine. Northern Arizona: Invasive/Noninvasive Cardiologists and Internal Medicine. Call Chris Warner, Panther Enterprises Physician Recruiting and Placement, (800) 235-7601.

NEPHROLOGIST–BC/BE, for Internal Medicine/Nephrology practice in San Francisco. Terms negotiable. Please send CV to A. Aronow, MD, 45 Castro St, San Francisco, CA 94114; (415) 565-6003.

ORTHOPEDIST–BC/BE, California licensed, needed for San Francisco based multispecialty medical practice. Primarily forensic medical practice (evaluation and expert witness evaluations in workers' compensation, personal injury, etc). Excellent opportunity for experienced clinician looking to emphasize evaluation and consultation practice as opposed to heavy treatment based practice. Full-time and part-time employment available, exceptionally high income potential, full benefits, and 401K. Submit CV and letter stating professional goals and availability to Administrator, 2040 Polk St, Box 337, San Francisco, CA 94109.

ROCKY MOUNTAIN WEST AND SOUTHWEST NEED PHYSICIANS. All specialties needed. Urban, rural, solo, group opportunities, all close to mountain recreation. Call Rita Longino at (800) 279-5267 or FAX CV to (800) 467-1246 or send CV to WHS, PO Box 2107, Corrales, NM 87048-2107.

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PHYSICIANS WANTED

COLORADO FAMILY PRACTICE PHYSICIAN

BC Family Physician to join a multisite community health center serving low income families in Northwest metropolitan Denver. Position includes faculty appointment at the University of Colorado Department of Family Medicine and resident training opportunities. Competitive salary and comprehensive fringe benefit package. Work in a teaching environment with an interdisciplinary team dedicated to promoting health in an underserved population. Please send CV to **CLINICA CAMPESINA FAMILY HEALTH SERVICES,** 1345 Plaza Ct N, Unit 1A, Lafayette, CO 80026. Or call Pete Leibig, Executive Director, at (303) 665-9310 for more information.

WESTERN MONTANA. BC/BE General Internist with interest in Primary Care wanted for active 50 plus physician multispecialty group. Unparalleled outdoor recreation and outstanding schools in university town of 45,000. Income guarantee, malpractice insurance, early partnership. Excellent fringe benefits. Position available now. Send CV to Administrator, Western Montana Clinic, PO Box 7609, Missoula, MT 59807.

TWO INVASIVE CARDIOLOGISTS AND FAMILY PHYSICIANS NEEDED. Unique opportunity. Gorgeous California central coast. Partnership within year. Send references/CV to Number 286, The Western Journal of Medicine, PO Box 7602, San Francisco, CA 94120-7602.

INTERNIST, BC/BE, to join four Internists in multispecialty practice in Portland suburb. Salary and benefits, with partnership available. Send CV to Beaverton Medical Clinic, Sterling Piepgrass, MD, 4690 SW Washington, Beaverton, OR 97229; (503) 644-3148.

FOR BEST RESULTS: CLASSIFIEDS. (415) 882-3376.

PHYSICIANS WANTED

THE SOUTHWEST IS CALLING

Leading medical providers in Arizona, Nevada, Utah, Colorado, and New Mexico have asked us to find the best available BC/BE physicians in the specialties of Orthopedic Surgery, Internal Medicine, Family Practice, Pediatrics, Urgent Care, OB/GYN, Psychiatry, Hematology/Oncology, Radiology, Occupational Medicine, ENT, MED/PED, Neurology, and Rheumatology. Top benefits, profit sharing, guarantee first two years, plus incentive pay, early shareholder. Please call CPR Tucson, (800) 658-9166, FAX (602) 322-2676, or in Phoenix, (800) 657-0354, FAX (602) 433-9548.

FAMILY PRACTICE, EMERGENCY MEDICINE, Internal Medicine, Locums, OB/GYN, Occupational Medicine, Pediatrics, and Urgent Care opportunities available in Minneapolis, St Paul, and leading communities within a 150-mile radius of the Twin Cities. Contact HealthSpan, Physician Services, 2810 57th Ave N, Minneapolis, MN 55430; (800) 248-4921 or (612) 574-7627.

SAN JOSE, CALIFORNIA. Busy academically affiliated hospital-based Occupational Medicine program with multidisciplinary focus is expanding practice in new clinic setting. Seeking full-time BC/BE experienced Occupational Medicine physician for advanced level clinical position. Competitive salary, excellent benefits. If interested, please send CV to Lynn E. Vail, MS, SCVMC, Division of Occupational Medicine, 750 S Bascom Ave, Ste 240, San Jose, CA 95128; (408) 299-8800, FAX (408) 993-1431.

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SAN FRANCISCO BAY AREA. Energetic, recently trained BC/BE Pediatrician needed for 18 physician satellite of Palo Alto Medical Clinic, a 160 physician multispecialty group with a national reputation for innovation and excellence. Broad practice in growing bay area community. Excellent location with convenient access to San Francisco and Stanford. Competitive compensation/benefits package. Early partnership. Please send CV to David Hooper, PAMC, Fremont Center, 39500 Liberty St, Fremont, CA 94538.

BOISE, IDAHO. IDAHO EMERGENCY PHYSICIANS is in the process of expanding our organization. We have two Urgent Care centers with plans to add an additional three centers by June 1994. We have full-time and part-time opportunities for experienced Primary Care physicians. Mid-level practitioners considered. Positions are salaried with superb benefits. Ownership potential. Ideal work week with flexibility. Extensive administrative support. Send résumé or CV for our return package. Recruiting Chairman, IEP, 2312 N Cole Rd, Ste B, Boise, ID 83704.

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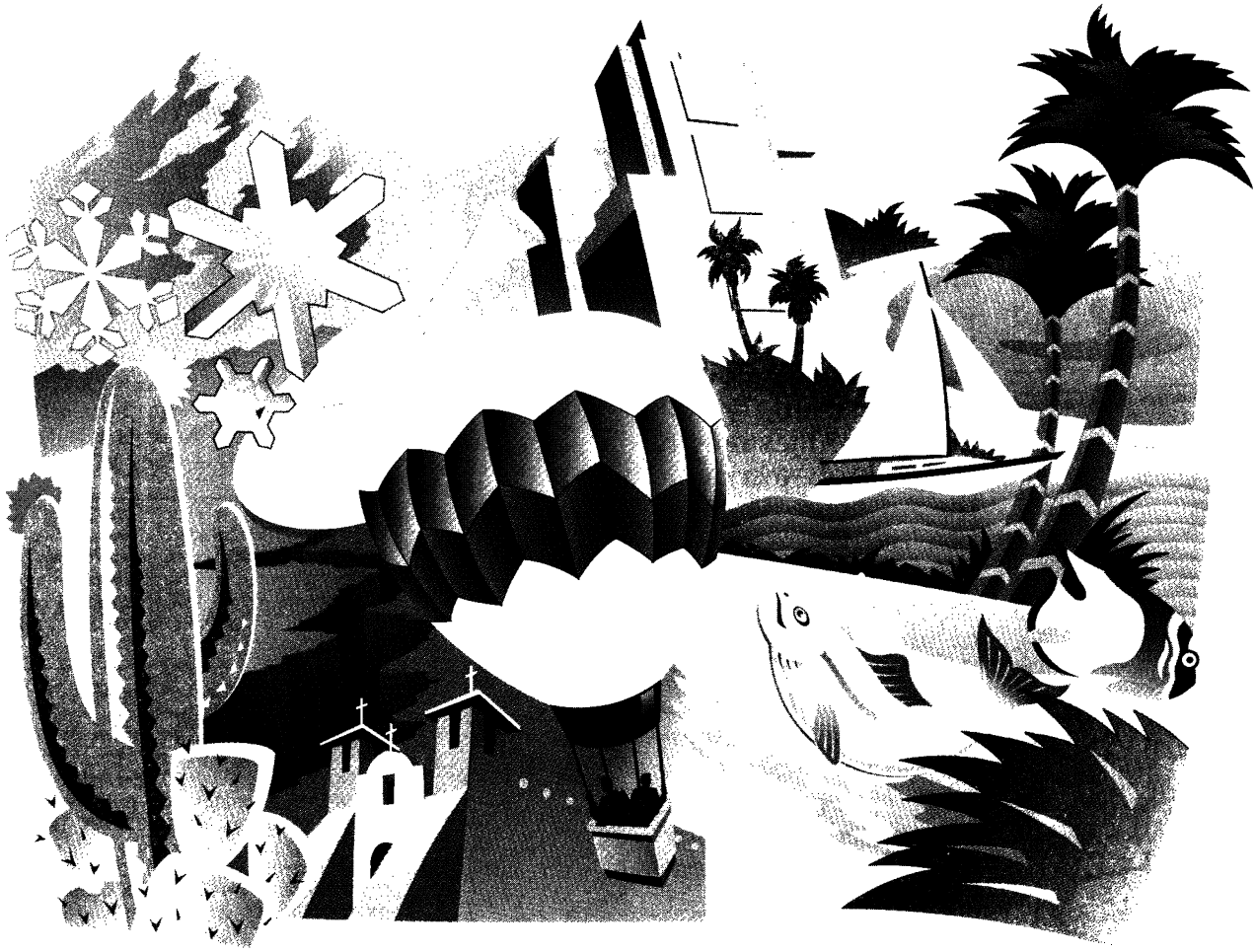

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(Continued from Page 392)

PHYSICIANS WANTED

Western States OPENINGS

Many multispecialty groups and hospitals have asked us to recruit for over 300 positions of various specialties. Both permanent and locum tenens. Send CV to **Western States Physician Services, 5627 E. Kings Canyon, Ste 156, Fresno, CA 93727, or call (800) 873-0786.**

EXCELLENT OPPORTUNITY FOR INTERNAL MEDICINE PHYSICIAN in private practice multispecialty physician group in San Francisco. Income guarantee. No investment. Forward CV to Box 263, The Western Journal of Medicine, PO Box 7602, San Francisco, CA 94120-7602.

CALIFORNIA MULTISPECIALTY. Urgent Care Director, Dermatologist, Radiologist, Otorhinolaryngologist, General Surgeon, Cardiologist, Internal Medicine, Pediatrician, Gastroenterologist, Orthopedist, General/Family Practitioner, Obstetrician/Gynecologist. Excellent opportunity for physicians to join 400 member multispecialty medical group serving the greater Los Angeles, San Fernando Valley, and Orange county areas. Over 40 locations. Large fee-for-service and prepaid practice, no Medi-Cal. Excellent compensation program based on guarantee plus incentive, profit sharing and pension plan. Group provides health, dental, life, and malpractice. Partnership in real estate and medical corporation available. Send CV to Ron McDaniel, Assistant Administrator, Mullikin Medical Center-5, 17821 S Pioneer Blvd, Artesia, CA 90701.

PHYSICIANS WANTED

IDAHO

Does having free time, three and four days off in a row, no on-call, a flexible schedule, and a competitive compensation package sound good to you? How about living in beautiful Idaho and experiencing a great life style? We are currently seeking full-time Family Practice physicians to staff our Family Practice/Minor Emergency clinics throughout Idaho. **Call Lora Meadows at (800) 688-5008 or send CV and inquiries to Primary Health, 727 E River Park Ln, Boise, ID 83706.**

PUGET SOUND. BC/BE Family Practitioners to affiliate with 100 plus physician multispecialty group, located 25 miles north of Seattle. Both walk-in clinic and traditional Family Practice position available. Opportunity for exceptional personal and professional lifestyle. Positions offer competitive salary with excellent benefits. Available immediately. Send CV to J. G. Finley, MD, The Everett Clinic, 3901 Hoyt Ave, Everett, WA 98201.

PHYSICIANS. We are a six site Community Health Center located in central California. We have an opening at our clinic near Bakersfield for an Internist and a Family Practitioner. Competitive salary, revenue from hospitalization, excellent benefits, daytime hours, and limited call. Loan repayment available through NHSC. Contact George Laven, MD or George Johnston at (805) 845-3731.

PHYSICIANS WANTED

EMERGENCY PHYSICIAN

CODY, WYOMING has a year round position available for an Emergency Physician beginning September of 1994. Work in the beautiful Rocky Mountain region, located only 50 miles from Yellowstone Park. Area abundant in fishing, camping, boating, and all outdoor sports. NO STATE INCOME TAX!! For more information **call (307) 578-2488** or send CV to **Gary Bishop, Administrator, West Park Hospital, 707 Sheridan Ave, Cody, WY 82414.**

ENT/HNS-UTAH. Small college town two hours from Alta and Snowbird. Nearby mountain biking, hunting, and desert exploring. Excellent 84-bed hospital with supportive medical staff. Well equipped office. Write to David Hilding, MD, Ste 1, Hospital Dr, Price, UT 84501.

HEAT WAVE? HAWAII, CALIFORNIA, UTAH, South Carolina, Florida, and Arizona clinics need Family Practitioners, Internists, Noninvasive Cardiologists and OBs. Hawaii—Hematologist/Oncologist, Gastroenterologist, $130,000. Benefits. Clear speech. CVs to LAM Associates, Dept W, 444 Hobron Ln, #207H, Honolulu, HI 96815-1229; Pat Lam, (800) 258-4526, (808) 947-9815, 11 am-8 pm PST.

CALIFORNIA. MONTEREY BAY. Full-/part-time positions available with Monterey Bay's largest and most successful Urgent Care network. Generous guarantee, incentive plan, and benefit package. Malpractice covered. Practice in California's most beautiful coastal recreational area. BC/BE Emergency Medicine or Family Practice specialists preferred. Contact Rob Colyn, VP of Personnel, Doctors on Duty Medical Clinics, 19000 Portola Dr, Ste 100, Salinas, CA 93908; (408) 455-2424.

ASSOCIATE IN PEDIATRICS. Kern Medical Center, Bakersfield, California, a teaching hospital affiliated with UCLA and UCI Schools of Medicine, seeks an Associate in the Division of Pediatrics. Prerequisites include eligibility or certification by the American Board of Pediatrics, strong interest in teaching and qualifications for faculty appointment in UCLA Department of Pediatrics. Comprehensive salary and benefit package. A part-time private practice is permitted. Medical center is in central California, a mid-sized urban community with moderate cost of living. Send CV and inquiries to Navin Amin, MD, Chairman, Department of Family Practice/Pediatrics, Kern Medical Center, 1830 Flower St, Bakersfield, CA 93305.

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PHYSICIANS WANTED

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Joyce Marks–President

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Joyce Marks-President
Marks Medical Placements
2170 Century Park East, #806
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Or Call: (310) 556-2126, FAX (310) 556-1604.

AT NO COST TO PHYSICIAN

FAMILY PRACTICE RESIDENCY. FULL-TIME FACULTY POSITION. University of Wyoming, Family Practice Residency Program–Casper. This outstanding rural Family Practice residency program seeks a physician scholar to join our faculty. The program has nine faculty members, 24 residents, and a competent support staff. The residency is affiliated with the Wyoming Medical Center, the referral hospital for the state, and the program is housed in an outstanding, freestanding facility. Responsibilities include resident supervision in ambulatory and inpatient settings, participation in scholarly activities, faculty development, and direct patient care. Requirements include BC in Family Practice, ability to obtain Family Practice credentials including Obstetrics, and a strong desire to teach rural Family Practice. Completion of a teaching fellowship in Family Practice and experience with Area Health Education Centers are highly desirable. Applications should include a current CV and three references. Academic rank in based on the individual's experience, and a competitive salary and benefits are offered. The community of Casper and the state of Wyoming can provide an enjoyable life-style which is unequaled elsewhere. The University of Wyoming is an equal opportunity/affirmative action employer. Please contact Joe K. Schoeber, MD, Program Director, University of Wyoming, Family Practice Residency Program–Casper, 1522 East "A" St, Casper, WY 82601; (307) 266-3076.

ENJOY THE GREAT SOUTHWEST. Thomas-Davis Medical Centers, one of Arizona's fastest growing multispecialty groups is seeking BC/BE Internal Medicine, Family Practice, OB/GYN, Hematology/Oncology, and Urgent Care Physicians for our Tucson location. 200 physicians strong, TDMC has provided health care services in Arizona for more than 75 years. For more information regarding this practice opportunity, contact William Trainor, TDMC, 6135 N 7th St, Phoenix, AZ 85014, or call (800) 539-2529, or FAX CV to (602) 530-6255.

BC/BE FAMILY PRACTITIONER with interest in OB and a commitment to caring for the underserved needed to join clinics in Grandview and Walla Walla, Washington, and Hermiston, Oregon. All clinics located in rural settings with abundant recreational activities. Competitive salary, Public Health Service loan repayment slots, and excellent benefit package including paid malpractice. Contact Mayling Chin, Recruiting Specialist, or Ann Garza, Director of Personnel at Yakima Valley Farm Workers Clinic, PO Box 190, Toppenish, WA 98948, or (509) 865-5898.

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CALIFORNIA
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IDAHO–NONINVASIVE CARDIOLOGIST. 18 physician, multispecialty clinic with attached 44-bed hospital, seeks noninvasive Cardiologist to join busy practice in a growing community. Facility is physician owned, partnership available after two years, above average compensation. Outstanding recreational opportunities. Close to Sun Valley and wilderness areas. Please send CV to Brent Bodily, PO Box 1233, Twin Falls, ID 83301; (208) 733-3700.

CALIFORNIA. Ambulatory Care/Family Practice-CEP is a partnership of Ambulatory Care and Emergency Medicine specialists. We currently staff nine free-standing clinics in northern, central, and southern California, and have upcoming openings for physicians specializing in Family Practice. We offer shared ownership, excellent compensation, health, and disability insurance, retirement program, and many other benefits. For more information, send CV or call John Gravette, CEP, 2101 Webster St, Ste 1050, Oakland, CA 94612; (800) 842-2619.

COASTAL CALIFORNIA–SAN LUIS OBISPO. Family Practice and Internal Medicine, BC/BE. Join our busy Primary Care group practice. Located midway between Los Angeles and San Francisco on the central coast of California. San Luis Obispo offers a variety of cultural/recreational activities, a beautiful coastline, vineyards, and a local university. Call or send CV to Fran Coughlin, RN, MS, Ambulatory Care Services, San Luis Obispo General Hospital, Box 8113, San Luis Obispo, CA 93403-8113. Phone (805) 781-4936, FAX (805) 781-1096.

GREAT FAMILY PRACTICE OPPORTUNITY in small town in the north San Francisco bay area. Practice–moderately paced, broad range Family Practice group. No medicaid. Competent and caring staff with very little turnover. Stable patient base. Affiliated with residency program. Excellent opportunity for growth. Call 1:4 with inpatient optional. Well equipped office with view of bay, next to state park and par course. Base salary plus productivity bonus. Willing to provide housing. One year contract with option for partnership. Community–best of both worlds; small town life within 30 minutes of San Francisco. Affordable housing, good schools, safe neighborhood. Four seasons climate with mild winter. Outstanding recreational and cultural amenities. Boating, windsurfing, biking, and fine restaurants. Requirements–BC/BE Primary Care, minimum one year contract. To start August 1, 1994. Please contact Walt Zaks, Family Health Center, 1440 Military West, Benicia, CA 94510 or phone (707) 745-0711.

DEADLINE FOR JUNE CLASSIFIEDS IS MAY 2, 1994

PHYSICIANS WANTED

THE VA MEDICAL CENTER, PRESCOTT, ARIZONA

is seeking a BC/BE Internist or Family Practice Physician. Regular hours. Experience with Holter monitors, treadmill testing, and/or endoscopy desirable but not necessary. Prescott is a lovely area with beautiful surroundings, clean air, pleasant lifestyle, wonderful dry four season climate. Interested physicians may call (602) 445-4860, ext 6640, or send CV to Chief, Medical Service, VA Medical Center, Prescott, AZ 86313.

EOE

WYOMING INTERNIST NEEDED. Step into full practice with established Internist with guaranteed salary first year, buy-in second year. Practice real Internal Medicine like the old days. Great small town life but close enough to a major metropolitan area. No state income tax. Incredible outdoor activities with camping, flyfishing, world-class skiing nearby. Send reply to Box 289, Western Journal of Medicine, PO Box 7602, San Francisco, CA 94120-7602.

PHYSICIANS. The California Department of Corrections has positions available for Internal Medicine, Primary Care, General Practice, and Family Practice at the California Correctional Center at Susanville in beautiful Lassen County in Northern California. For more information, contact Stephen O'Barr, (916) 257-2181, ext 1213, or FAX your résumé to (916) 322-5864. EOE.

FAMILY PRACTICE. BC/BE PHYSICIANS sought by well established, physician-guided managed health care provider in Arizona. Primary Care environment. Phoenix and Tucson area opportunities. Shared call, predictable hours, attractive salary, outstanding benefits, and incentive programs. For more information, call (800) 535-4347 or send CV to FHP Health Care, Professional Staffing, PO Box 52078, Phoenix, AZ 85072-2078. FHP may also have clinical and management opportunities available in California, Utah, New Mexico, Nevada, and Guam. An equal opportunity employer M/F/D/V.

EMERGENCY MEDICINE UNIVERSITY POSITION. The University of California, Davis, School of Medicine, is recruiting for a full-time faculty. The position will be at the Assistant or Associate Professor level. The Division of Emergency Medicine and Clinical Toxicology is undergoing rapid academic development. A residency training program in Emergency Medicine was begun in 1990 and currently has 24 residents. The UCDMC Emergency Department provides comprehensive emergency service and is a major trauma center in northern California. The Department is a Paramedic Base Station and Training Center, and in addition, has an active helicopter service and regional poison center. Candidates must be BC/BE in Emergency Medicine and be eligible for licensure in California. A letter outlining interests and experience in addition to a CV and the names of five references should be sent to Robert W. Derlet, MD, Chair, Emergency Medicine Search Committee, FOLB I, University of California, Davis, Medical Center, 2315 Stockton Blvd, Sacramento, CA 95817. Opened until filled. No applications will be accepted after April 30, 1994. The University of California is an Affirmative Action/Equal Opportunity Employer.

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Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter²). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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AVAILABLE ON MEDI-CAL

Effective lipid management doesn't have to be tough

- Improves key lipids — significant reduction in LDL-C[1]
- Excellent safety profile
- Easy for patients — once-daily dosing, well tolerated
- Usual dose: 20 mg once daily at bedtime, with or without food

PRAVACHOL®

pravastatin sodium 20 mg tablets

PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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